UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,344	09/02/2005	David J. Kyle	08717.0012	1584

22852 7590 06/05/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
BERTOGLIO, VALARIE E	
ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
06/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,344	KYLE ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *4-14,18-33,37-42,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,15-17,34-36 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04/22/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 05/07 + 04/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-3, 15-17, 34-36 and 43 in the reply filed on 04/19/2007 is acknowledged. The traversal is on the ground(s) that Applicant is requiring restriction within claims 26,39 and 40 but not claims 1-3 and 15-17 and that issuing a restriction within a claim is tantamount to refusal to examine that which Applicant regards as their invention. This argument is relevant to Groups VII-IX. Claim 26 is drawn to a feed comprising multiple recited components. This is not found persuasive because the dependent claims limit the feed to comprising only one of the components listed in claim 26, which is a structurally distinct feed that will have different effects on different characteristics in the shrimp. If claim 30, for example, were drawn to the feed of claim 26 wherein the DHA content is limited as recited, and claim 32 were limited to the feed of claim 26 wherein the lycopene content is limited as recited, then the claims would be grouped together as the feed of claims 310 and 32 would both comprise DHA and lycopene. However, as claimed, claim 39 comprises DHA and not lycopene. The feed of claim 32 comprises lycopene and not DHA. Thus, restriction as set forth in the restriction requirement is deemed appropriate.

Applicant also argues that it would not be a burden to search the groups together. Search burden is not germane to examination of applications filed under 35 USC 371. However, such a search burden is , in fact, present as, for example, claim 1 is generically drawn to a shrimp having a high DHA content. A search for said shrimp in the literature would not necessarily reveal shrimp feed comprising lutein.

Applicant's argument that less than the entire scope of the claims is covered by Groups I-IX is not clear.

It is noted that Applicant is accurate in concluding that claim 42 was included in group I rather than claim 43, as a result of a typographical error (see page 10 of Applicant's Remarks).

The requirement is still deemed proper and is therefore made FINAL.

Applicant has added claims 44 and 45. The newly submitted claims 44 and 45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 44 is drawn to a shrimp comprising both the increased DHA of Group I in addition to an altered carotenoid content. The shrimp are distinct in their composition and are obtained through different methods, namely feeding with a feed having a different composition. Claim 45 is drawn to a shrimp depleted in cholesterol in addition to having other unrelated compositional limitations that are not related to the DHA level of Group I. The shrimp are distinct in their composition and are obtained through different methods, namely feeding with a feed having a different composition.

Accordingly, claims 44 and 45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-45 are pending. Claims 1,15,24,and 31-33 are amended. Claims 4-14,18-33, 47-42,44 and 45 are withdrawn as being drawn to a nonelected invention. Claims 1-3, 15-17, 34-36 and 43 are currently under consideration. Claim 43 is being examined to the extent that it reads on use of a shrimp comprising high-DHA. Other recited limitations are withdrawn as being drawn to non-elected inventions.

Specification

The disclosure is objected to because of the following:

The specification fails to provide a brief description of Figure 1.

Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

Appropriate correction is required.

The use of the trademark AquaGrow at page 13 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is advised that notice applies to use of any other trademarks that may be present throughout the specification, as well.

Claim Objections

Claim 36 objected to because of the following informalities: The terms "dinoflagellates" and "chytrids" appear to be misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3,15-17 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but

rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The claims are drawn to shrimp, raised aquaculturally comprising DHA at levels higher than about 12.5 ug/g fresh weight (claims 1-3) or comprising a DHA/EPA ratio greater than 2.0 (claims 15-17).

The specification teaches feeding shrimp either *Crypthecodinium* sp or *Schizochytrium* sp of algae (page 13, paragraph [048]. The specification shows a modest increase in percent DHA composition in shrimp fed the alga in comparison to those fed a fish oil supplement. In fact, this increase over the control diet appeared in only 1 out of the 2 samples measured (see Table 2 at page 19). The specification does not teach what the percent DHA is relative to. It could be percent total fatty acid, percent dry weight, or percent fresh weight. Thus, not only does the data appear to be not statistically significant especially in light of a sample size of 2, it is not clear how the result relate to the claimed 12.5 –50 ug/g fresh weight.

The art at the time of filing had revealed that some algal species were a food source that can lead to increases in the DHA and EPA composition of shrimps [see for example, Thinh *et al*, **Aquaculture**, 1999, 170:161-173]. However, not all algae lead to such a benefit and those that do enhance DHA content of shrimp, do so to varying degrees dependent upon the DHA content of the algae. Furthermore, even shrimp with higher DHA levels as well as those with control diets failed to have a DHA/EPA content even remotely close to 2.0 as required by the claims.

Thus, the state of the art holds that it is unpredictable whether any particular algae will cause an increase in DHA in shrimp fed the algae and the degree of the increase is also variable. The claims require DHA levels of at least 12.5 ug/g fresh weight of shrimp or a DHA/EPA ratio of at least 2.0. Based on the state of the art, only certain feeding conditions would meet these limitations and no feeding conditions have been made of record that lead to a DHA/EPA of at least 2.0. The specification teaches feeding *Crypthocodinium sp.* However, the specification does not teach whether this species of algae results in an increase in DHA to at least 12.5 ug/g fresh weight or the DHA/EPA ratio to at least 2.0. The specification only teaches a modest increase in DHA in 1 out of 2 samples in terms of some percentage relative an unknown standard. It would require undue experimentation to determine how to make the shrimp as claimed comprising at least 12.5 ug/g fresh weight or having a DHA/EPA ratio of at least 2.0.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high DHA shrimp" is unclear. Not only does the claim fail to clearly set forth that the shrimp has a high DHA content, the metes and bounds of what encompassed are unclear as the specification fails to define what "high-DHA shrimp" are. The term "high" is a relative term and the claims and specification fail to set forth what the term is relative to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-3, 34-36 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Thinh *et al* (1999, **Aquaculture**, 170:161-173).

It is noted that the instant rejection is not in contradiction to the lack of enablement rejection set forth above. The claims are not enabled to the extent that one cannot determine whether the support in the specification correlates to the limitation of at least 12.5 ug/g fresh weight. Similarly, one cannot determine how the dry weight values of the art correlate to the fresh weight values claimed.

The claims are drawn to shrimp, raised aquaculturally comprising DHA at levels higher than about 12.5 ug/g fresh weight (claims 1-3) or comprising a DHA/EPA ratio greater than 2.0 (claims 15-17). Claim 34 is drawn to a method of making an organic shrimp comprising feeding microalgal DHA to the shrimp. Claim 43 is drawn to a shrimp having "high DHA".

The specification teaches increasing the DHA content of shrimp by feeding microalgae. To this extent the following art applies.

Thinh *et al* taught feeding multiple algal species that comprise DHA to shrimps. Thinh found that some algal species resulted in increased levels of DHA (22:6n-3) (see Table 4). Because the shrimps of Thinh were fed in a manner similar to those of the instant invention, the specification and claims fail to distinguish any identifying characteristics of the shrimp claimed and those of Thinh. It cannot be determined arithmetically that the increased DHA levels measured in terms of total fatty acids correlate to at least 12.5 ug/g fresh weight as claimed, however, in evidence to the contrary, the shrimp of Thinh and those claimed are structurally identical as they were each fed microalgae. Furthermore, because the shrimp of Thinh showed increased DHA over control fed shrimp, these are considered to fall within the limitation of "high DNA shrimp".

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical means or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best 562 F.2d sat 1255, 195 USPQ 433. See M.P.E.P 2112.01.

2) Claims 1-3, 34-36 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Barclay *et al* (1996, IDS).

It is noted that the instant rejection is not in contradiction to the lack of enablement rejection set forth above. The claims are not enabled to the extent that one cannot determine whether the support in the specification correlates to the limitation of at least 12.5 ug/g fresh weight. Similarly, one cannot determine how the dry weight values of the art correlate to the fresh weight values claimed.

The claims are drawn to shrimp, raised aquaculturally comprising DHA at levels higher than about 12.5 ug/g fresh weight (claims 1-3) or comprising a DHA/EPA ratio greater than 2.0 (claims 15-17). Claim 34 is drawn to a method of making an organic shrimp comprising feeding microalgal DHA to the shrimp. Claim 43 is drawn to a shrimp having "high DHA".

The specification teaches increasing the DHA content of shrimp by feeding microalgae. To this extent the following art applies.

Barclay *et al* taught feeding Schyzochytruim algal species that comprise DHA to shrimps. Barclay found that some algal species resulted in increased levels of DHA (22:6n-3) (see Table 2) to 1.5 percent of total fatty acids or 0.1% of dry weight. Because the shrimps of Barclay were fed in a manner similar to those of the instant invention, the specification and claims fail to distinguish any identifying

characteristics of the shrimp claimed and those of Barclay. It cannot be determined arithmetically that the increased DHA levels measured in terms of total fatty acids correlate to at least 12.5 ug/g fresh weight as claimed, however, in evidence to the contrary, the shrimp of Barclay and those claimed are structurally identical as they were each fed microalgae. Furthermore, because the shrimp of Barclay showed increased DHA over control fed shrimp, these are considered to fall within the limitation of "high DNA shrimp".

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical means or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best 562 F.2d sat 1255, 195 USPQ 433. See M.P.E.P 2112.01.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Valarie Bertoglio
Primary Examiner
Art Unit 1632